

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES	

**DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE
CERTAIN OPINIONS AND TESTIMONY OF BARRY SCHLAFSTEIN, M.D.**

Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), submit this response to *Plaintiffs' Memorandum in Support of their Motion to Exclude Certain Opinions and Testimony of Barry Schlafstein* [ECF No. # 2019] (the "Motion"). The cases to which this Response applies are identified in Ex. A.

Dr. Barry Schlafstein, M.D., is a board-certified urogynecologist with over 25 years of experience treating women for pelvic organ prolapse and stress urinary incontinence. Plaintiffs seek to exclude or limit Dr. Schlafstein's opinions on four grounds: (1) he is not qualified to offer "design" opinions; (2) his opinions based on his personal experiences are not reliable; (3) he is not qualified to offer opinions about warnings; and (4) his opinions are unreliable because he did not seek out contradictory information. These arguments are without merit, and the Court should deny the Plaintiff's Motion.

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1–3 (S.D.W. Va. July 8, 2014).

II. Dr. Schlafstein Does Not Need to Be Qualified as a “Design” Expert to Offer His Opinions About Safety and Effectiveness.

To the extent Plaintiffs seek to exclude Dr. Schlafstein’s “design” opinions, the Motion should be denied. Dr. Schlafstein has not disclosed any design opinions, and there are no design opinions contained in his reports. Dr. Schlafstein’s opinions go to the clinical safety and effectiveness of TVT, TVT-O, Prolift, and Prolift+M. Contrary to Plaintiffs’ arguments, these opinions are reliable and well within the scope of Dr. Schlafstein’s expertise.

In his reports, Dr. Schlafstein, relying on societal position statements, peer-reviewed literature, and his own extensive clinical experience, opines that TVT, TVT-O, Prolift, and Prolift+M are safe and effective for their intended uses. Pls.’ Motion Ex. B, TVT Report at 10–11; Pls.’ Motion Ex. C, Prolift Report at 12. The fact that these opinions undermine Plaintiffs’ design defect claims does not require Dr. Schlafstein to be a “design expert.” Dr. Schlafstein does not offer opinions about biomaterials, pore size, mesh construction, or other engineering-related topics. Instead, his opinions go to the clinical risks and benefits of these products, a topic about which Dr. Schlafstein, as an experienced urogynecologist, is qualified to opine. *See generally Trevino v. Bos. Sci Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *13 (S.D.W. Va. Apr. 28, 2016) (“Doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs”) (internal alterations and quotation marks omitted)). Additionally, to the extent Dr. Schlafstein’s opinions are “design” opinions, his years of experience treating pelvic floor disorders using mesh qualifies him to offer opinions about

product design.¹ *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013) (finding that expert urogynecologist was qualified to render opinions on “product design, testing, and materials” because the expert’s “extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on such issues, notwithstanding his lack of expertise in the particular areas of product design or biomaterials”).

In this MDL, this Court has consistently noted that expert gynecologists or urologists, by virtue of their experience as specialists, are qualified to opine about the risks and benefits of pelvic organ prolapse and stress urinary incontinence devices, without requiring that these physicians also be “design” experts. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014) (“[A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT–O”); *Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *7 & n.3 (S.D.W. Va. Apr. 24, 2015) (finding urologist qualified to offer opinions about risks and benefits of polypropylene midurethral sling); *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *20 (S.D.W. Va. Jan. 15, 2014) (finding urogynecologist qualified to opine about whether TVT was suitable for its intended use).

There is no reason in this case to depart from these prior rulings. Dr. Schlafstein has more than 25 years of experience as an OB/GYN. Pls.’ Motion Ex. B, TVT Report at 1–2; Resp. Ex. B, Schlafstein 4/04/16 Dep. Tr. 55:19–61:2. He has personally placed over 950 TVT products for the treatment of stress urinary incontinence and performed over 630 procedures using

¹ In the event Dr. Schlafstein’s opinions could be considered “design” opinions, the Court should not exclude these opinions based solely on a concession at his deposition that he was not an expert on “design,” given that he clearly did not interpret the word “design” to include opinions about safety and effectiveness. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 637 n.18 (S.D.W. Va. 2013) (refusing to strike biomaterials expert based on expert’s concession that he was “not an expert in the design of pelvic mesh” where it was “obvious” that expert did not consider his biomaterials opinions to be “design” opinions).

transvaginal mesh for the treatment of pelvic organ prolapse. *Id.* at 108:5–18; Pls.’ Motion Ex. B, TVT Report at 3–4. He is a fellow in the American College of Obstetrics and Gynecology and is a member of the American Urogynecological Society, among other medical organizations. *Id.* at 1. He was among the first group of physicians to become board-certified in the subspecialty of female pelvic medicine and reconstructive surgery, also known as urogynecology. Resp. Ex. B, Schlafstein 4/04/16 Dep. Tr. 78:23–80:10. These credentials establish that Dr. Schlafstein is qualified to offer opinions about the risks and benefits of the TVT and Prolift families of products.

III. The Court Should Allow Dr. Schlafstein to Testify About His Personal Experience with Mesh Implants as this Experience Supports His Opinions.

Plaintiffs attempt to preclude Dr. Schlafstein from testifying about his personal experiences implanting nearly 1000 TVT products and over 630 pelvic organ prolapse meshes. Plaintiffs argue that Dr. Schlafstein is offering inadmissible, anecdotal “complication rate” opinions based on his personal experience. Nothing in his reports suggests that Dr. Schlafstein will offer opinions about the specific rates of complications he has personally observed in his practice. Plaintiff’s Motion should therefore be denied as moot to the extent it seeks to exclude opinions about complication rates among Dr. Schlafstein’s own patients.

However, Dr. Schlafstein may reliably draw on this personal experience, along with his review of peer-reviewed literature, to support his opinions regarding mesh-related complications. This Court has consistently allowed gynecology experts to offer opinions based, in part, “on the fact that [the expert] has observed minimal complications in his clinical practice.” *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014). Dr. Schlafstein should likewise be allowed to testify about his personal clinical experience, as this experience forms part of the basis for his opinions.

IV. As an Experienced Urogynecologist, Dr. Schlafstein Is Qualified to Offer Opinions About the Adequacy of Warnings.

Plaintiffs attempt to distort a sound bite from Dr. Schlafstein's deposition to argue that he is not qualified to offer warnings opinions. In the deposition testimony quoted by Plaintiffs, Dr. Schlafstein stated that he was an expert "in the context of how I use these products and how I warn patients," but not in the context of regulatory requirements for IFUs or in the reasons for the 2015 changes to the TVT IFU. Pls.' Motion Ex. D, Schlafstein 4/14/16 Dep. Tr. 196:12–14, 210:23–211:11. Nothing in this testimony renders Dr. Schlafstein unqualified to offer his opinions about the adequacy of Ethicon's warnings. Instead, Dr. Schlafstein is highly qualified by his decades of experience implanting pelvic mesh devices and counseling women on the risks and benefits of these devices to offer opinions about warnings.

As noted above, Dr. Schlafstein has extensive experience in the field of pelvic floor repair using mesh, including the risks and complications associated with pelvic floor procedures. As this Court has noted, "[d]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger*, 2015 WL 1887222, at *15 (internal alterations and quotation marks omitted). In addition to the risks and complications he has personally observed in his practice, Dr. Schlafstein's warnings opinions take into account his review of peer-reviewed medical literature, discussions with colleagues, and attendance at medical meetings. Pls.' Motion Ex. B, TVT Report at 1; Pls.' Motion Ex. C, Prolift Report at 1. From his personal experience, training, education, and review of peer-reviewed literature, Dr. Schlafstein is familiar with *all* of the potential risks and complications of TVT, TVT-O, Prolift, and Prolift+M and is therefore qualified to opine on whether the IFUs adequately warned of these risks.

V. Dr. Schlafstein's Alleged Failure to Specifically Seek out Contradictory Position Statements Does Not Render His Opinion Unreliable.

Plaintiffs attack the reliability of *all* of Dr. Schlafstein's opinions based on the sole allegation that he did not specifically look for information that contradicted his opinions. The only evidence relied upon by Plaintiffs to support their argument is that Dr. Schlafstein did not cite to position papers from professional societies that disagree with his opinions. Plaintiffs completely ignore the dozens of peer-reviewed studies cited by Dr. Schlafstein that demonstrate the reliability of Dr. Schlafstein's opinions, notwithstanding any alleged failure to review other particular documents. This literature, along with Dr. Schlafstein's extensive personal experience, establishes the reliability of his opinions, even in the face of hypothetical position statements disagreeing with his conclusions.

Further, Plaintiffs do not cite any case law for the proposition that, under *Daubert*, an expert is required to specifically seek out and review information that contradicts his own opinions. Rather, this Court has previously rejected this argument, noting that an expert's "failure to review or cite particular documents . . . goes to the weight of his opinion, not its admissibility." *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 538 (S.D.W. Va. 2014) (quoting *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 at *51 (S.D.W. Va. Sept. 29, 2014)); accord *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D.W. Va. 2014). The Court has also noted that an expert's "clinical experience and review of the scientific literature are sufficiently reliable bases in forming" the opinion that a pelvic mesh device is safe and effective. *Tyree*, 54 F. Supp. 3d at 585. In light of Dr. Schlafstein's extensive clinical experience and his review of the relevant medical literature, the Plaintiffs' reliability argument has no merit.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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